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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,638	10/17/2003	Robert H. Harris	13095B	2598

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GARDEN CITY, NY 11530

EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/688,638

Applicant(s)

HARRIS, ROBERT H.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-49, 54, 57 and 68-72 is/are pending in the application.  
4a) Of the above claim(s) 44-46 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 35-43, 47-49, 54, 57 and 68-72 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

Applicants' election is acknowledged, i.e., the following compound:



Applicants have argued that if the "election of species" becomes a restriction requirement, it will be traversed. In response, no claim will be withdrawn that encompasses the elected specie. It is true that claims 44-46 are now withdrawn from consideration, since they do not encompass the elected specie. However, if claim 35 is found allowable in its present form, claims 44-46 will be rejoined therewith; if claim 35 found allowable in amended form, and if that amended form encompasses the subject matter of claims 44-46, these latter claims (44-46) will be rejoined with the elected claims.

Claims 35-49, 54, 57, 68-72 remain pending. Claims 35-43, 47-49, 54, 57, 68-72 are examined in this Office action.

. . . . .

The following abbreviations are used hereinbelow:

"EWG" represents an electron-withdrawing group

"EDG" represents an electron-donating group

"EWG/EDG" signifies that a group may be either electron-donating, or electron-withdrawing



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-39 are rejected under 35 U.S.C. §102(e) as being anticipated by Bialer (USP 6,028,102).

Bialer discloses (col 3, line 40; col 2, line 20) that the following glycine derivative can be used to treat bipolar disorder:



Thus, the claims are anticipated.



The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 35-43, 47-49, 54, 57, 68-72 are rejected under 35 U.S.C. §103 as being unpatentable over Kohn (USP 5,378,729) in view of Post R M (*Psychopharmacology* 128 (2) 115-29, 1996) or Yang Y. Y. (*Psychiatry and Clinical Neurosciences* 52 (4) 429-31, 1998) or Keck P. E. (*J. Neuropsychol and Clinical Neurosci* 4, 395-405, 1992).

Kohn discloses the compounds to which the claims are directed. Kohn also discloses that the compounds are effective anticonvulsants. Kohn does not teach treatment of bipolar disorder. Each of the secondary references discloses that anticonvulsants can be used to treat bipolar disorder.

Thus, it would have been obvious to one of ordinary skill that the compounds of Kohn can be used to treat bipolar disorder.

Claim 35 is rejected under 35 U.S.C. §103 as being unpatentable over Brennan (USP 6,716,810).

Brennan discloses N-acetylated peptides that are cyclic or acyclic. See, for example, the following locations: col 10, line 20, col 24, line 39, and col 27, line 35+. Also disclosed (col 55, line 25) is that the compounds can be used to treat bipolar disorder.

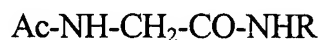
The claims are rendered obvious for the case of "R" representing hydrogen that is substituted with EWG/EDG, or for the case of "R" representing alkyl that is substituted with EWG/EDG.



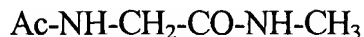
Claim 35 is rejected under 35 U.S.C. §103 as being unpatentable over Maccocchi (USP 6,511,963).

Maccocchi discloses (tables I and II, cols 21-24) various peptides which bear an acetyl group at the N-terminus. Also disclosed (col 11, line 34; col 108, line 2) is that the disclosed peptides can be used to treat bipolar disorder. Maccocchi does not disclose that the propensity of a peptide to donate or withdraw electrons is perceptively different from that of a hydrogen atom.

The issue here concerns the term "electron withdrawing...or ...donating group", used in claim 35 in reference to substituent variable "R". For the case of  $R^1 = \text{methyl}$ ,  $R^2$  and  $R^3 = \text{hydrogen}$ , and  $n = 1$ , claim 35 is drawn to the following:



Suppose, for purposes of discussion, that "R" represents methyl. Claim 35 then encompasses the following:



Next, suppose that the methyl group is substituted once with benzyl, and once with the following:  $\text{-COCH(Me)CONHCH(COOH)CH}_2\text{-COOH}$

The result is the following peptide: Ac-Gly-Phe-Ala-Asp

The point is simply that claim 35 encompasses virtually any peptide of any length, so long as the N-terminal *alpha*-amino group bears an acetyl group (or other alkanoyl group). The physical organic chemist of ordinary skill would immediately recognize that a peptide, or almost any portion thereof, is electronically different from hydrogen. Even the effect of a relatively "neutral" (electronically neutral, that is) substituent such as methyl on the ionization of benzoic acid was measurable given the technology available in the 1950's.

Thus, the claims are rendered obvious.



Claim 35 is rejected under 35 U.S.C. § 103 as being unpatentable over Somers (USP 6,034,216).

Somers discloses a compound at col 126, line 45+. Also disclosed (col 29, line 38) is that the compound can be used to treat depression. Somers does not disclose that the compound can be used to treat bipolar disorder.

The issue here is whether treatment of the depressive episodes of a bipolar patient would qualify as being therapeutically effective even if the patients' manic episodes remain unaffected by the treatment. For the patient who exhibits manic and depressive episodes with equal frequency, the treatment of Somers would be effective about 50% of the time. It is the position of the examiner (and most applicants, for that matter) that if a treatment is effective 50% of the time, it qualifies as "therapeutically effective".

Thus, the claim is rendered obvious.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800